BIOMET INC

K080528

JUN 17 2008

510(k) Summary
E-Poly™ Tibial Bearings

Preparation Date: February 22, 2008

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Melissa Steinwedel
Regulatory Specialist

Proprietary Name: E-Poly™ Tibial Bearings

Common Name: Vitamin E Polyethylene Tibial Bearings

Classification Name: Cemented semi-constrained polymer/metal/polymer knee prosthesis (888.3560), JWH

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

Maxim Accel Knee System	K023546	Biomet Inc.
Maxim Accel (Vanguard™) PS & Bearings	K041046	Biomet Inc.
Vanguard™ Anterior Stabilized Tibial Bearings	K050222	Biomet Inc.
100kGy E-Poly™ MaxRom Acetabular Liners	K070364	Biomet Inc.

Device Description: The E-Poly™ Tibial Bearings are provided in five sizes. Each size comes in five thicknesses. (There are five basic styles of the E-Poly™ Bearings which are intended to be used with previously cleared Biomet knee products.)

Indications for Use:

1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved.
2. Correction of varus, valgus, or posttraumatic deformity.
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

Intended Use:
For cemented and un-cemented use.

Summary of Technologies: The E-Poly™ UHMWPE tibial bearings are highly-crosslinked to improve wear resistance, and infused with vitamin E to stabilize free-radicals and prevent oxidative degradation.

Non-Clinical Testing: Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

Clinical Testing: None provided as a basis for substantial equivalence.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 2008

Biomet Orthopedics, Inc.
% Mr. Gary Baker
56 East Bell Drive
P.O. Box 587
Warsaw, IN 46581

Re: K080528
Trade/Device Name: E-Poly Tibial Bearings
Regulation Number: 21 CFR 888.3560
Regulation Name: Cemented semi-constrained polymer/metal/polymer knee prosthesis
Regulatory Class: Class II
Product Code: OIY, JWH, MBH, MBV
Dated: June 4, 2008
Received: June 6, 2006

Dear Mr. Baker:

This letter corrects our substantially equivalent letter dated June 17, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K080528

Device Name: E-Poly™ Tibial Liners

Indications for Use:

1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved.
2. Correction of varus, valgus, or posttraumatic deformity.
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

For cemented and un-cemented use.

Prescription Use YES (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use NO (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080528